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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,416	PHILLIPS ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-15,18 and 21-39* is/are pending in the application.

4a) Of the above claim(s) *1-4,11-15,22 and 24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,18,21,23 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/05/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's reply filed 05/13/2005 has been received. Claims 5-7,16,17,19 and 20 have been cancelled. Claims 8-10,18,21 and 23 have been amended. Claims 36-39 have been added. Claims 1-4,11-15,22 and 24-35 are withdrawn. Claims 1-4, 8-15,18 and 21-39 are pending and claims 8-10,18,21,23 and 36-39 are under consideration in the instant office action.

Election/Restrictions

This application contains claims 1-4,11-15,22 and 24-35 drawn to an invention nonelected with traverse in the restriction mailed 06/25/2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The amendment filed 05/13/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

Applicant has amended the specification at page 11, paragraph 4 and page 12, paragraph 1 to incorporate US Provisional Application 60/084194. This reference is not considered new matter because the original specification incorporated USSN 08/971310 by reference, which was converted to the Provisional Application 60/084194. However, the additional references are considered new matter. The references include a second provisional application (60/084949), a utility application claiming priority to the two provisional applications (09/193,834) and a second utility application that is a continuation of the first utility application (09/885,816; published as US Patent 6,815,185). There is no evidence that these newly referenced applications

were contemplated as being part of the original specification as an incorporation by reference. The reference to "U.S. Patent no. 6,815,185 issued November 9, 2004, which is based on U.S. Patent Application No. 09/885,816, filed June 19, 2001, which is a continuation of U.S. Application No. 09/193,834, filed November 17, 1998, now abandoned, which claims priority to provisional application no. 60/084,949, filed on May 11, 1998, and provisional application no. 60/084,194, the disclosure of provisional application no. 60/084,194" should be replaced with "US Patent Application No. 08/971,310, which was converted to provisional application no. 60/084194". The other applications should not be included.

Claim Objections

The objection to claims 10 and 17-20 as set forth on page 8 of the office action mailed 01/13/2005 is withdrawn in light of Applicant's amendments to the claims.

Claim 10 is objected to because of the following informalities:

Claim 10 requires a pseudopregnant mouse to give birth. A pseudopregnant mouse is not pregnant, and cannot give birth. Appropriate correction is required.

Claim 18 is objected to because of the following informalities:

Claim 18 is drawn to the transgenic mouse of claim 8. However, claim 8 is drawn to a cell, not a mouse. Appropriate correction is required.

9 9 OK

should dep fm clm 8

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Utility

Claims 8-10,18,21,23 and 36-39 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The rejection set forth on pages 8-14 of the previous office action mailed 01/13/2005 is maintained for claims 1-4, 8-15,18 and 21-35 and is applied to newly added claims 36-39 for reasons of record.

Definitions:
[from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

See also the MPEP § 2107 - 2107.02.

The instant specification has discussed that the mice of the instant invention can be used as models of disease to screen for drug therapies and as a tool for studying the function of a gene

encoding SEQ ID NO:1. As set forth in the previous office action, these uses fail to meet the standards of a specific, substantial and well-established utility required under 35 U.S.C. 101. In summary, the utilities provided by Applicant for the claimed mouse are not specific or substantial and therefore are not well established because the use of the mouse in screening for drugs to treat an unknown disease is not specific. The use for the claimed mouse in characterizing the function of a gene encoding SEQ ID NO:1 is not substantial. The teachings in the specification failed to define the identity of the gene that correlates to the EST set forth by SEQ ID NO:1. Noteably, SEQ ID NO:1 is a human EST for which the specification provides no characterization or identification of a mouse homolog. As a result, it is not even known what gene is being knocked out in the claimed mouse. Further basis for this rejection is further set forth in the previous office action and in the guidelines above.

Applicant's arguments have been fully considered and are not found persuasive. Applicant has argued that the Patent Office guidelines state that a rejection for lack of utility may not be imposed where an invention has a well-established utility or is useful for any particular practical purpose (pages 9-14). Applicant cites excerpts from an NIH website, Austin et al., 2004, Lewin's Genes VII, and others (pages 11-14 of Applicant's response) in establishing that knockout mice are invaluable tools of scientific research. Applicant also cites the MPEP in discussing the utility of research tools (pages 12-13 of Applicant's response; MPEP 2107.01, I). Applicant cites Langer to support the argument that the assertion of a utility is credible unless the logic underlying the assertion is flawed or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion (pages 9-10). Applicant maintains that rejections under 35 USC 101 have rarely been sustained by the federal courts (page 10). In

general, Applicant does not understand how the invention cannot have utility when the invention is being used by one of skill in the art and has clearly been accepted as useful by several leaders in the field of transgenic technology.

In response, the instant invention has failed to meet the requirements of possessing a well-established utility and for a use with any particular practical purpose. A well-established utility and a utility with a particular practical purpose is one that is specific and substantial (see MPEP 2107(II)(A)(3)(ii) and MPEP 2107 (II)(B)(1)). The utility of the instant invention is neither specific nor substantial for reasons of record. Applicant is reminded that the utility guidelines (see above) expressly state that utilities requiring further research to identify or reasonably confirm a use do not define substantial utilities. Examples of uses that are not considered substantial utilities include basic research in studying the claimed product and use to screen for therapeutics for an unspecified disease. The use of the invention by the skilled artisan does not impart patentability or patentable use on the invention for reasons set forth above.

With specific respect to Applicant's applied references, the validity of the opinion of the NIH, Ben Lewin, Austin et al. and others with respect to the value of the knockout mouse in determining gene function is not questioned. However, the use of a mouse to determine gene function, as set forth above, does not meet the requirement that a utility be specific and substantial, and therefore, does not fulfill the requirements of utility under 35 USC 101. With respect to MPEP 2107.01, I, a gas chromatograph is a research tool with a well-defined function and highly specific use that does not necessitate further study of itself. It may be that a gas chromatograph may be used for a wide variety of analyses; however, this does not change its specific use for analyzing a sample. In contrast, the claimed invention is not a general tool for

analyzing other samples and, at most, serves to study the function of a single gene. In this respect, the utility of a knockout mouse cannot be compared to a gas chromatograph.

Finally, the credibility of the alleged general use for elucidating gene function is not the basis of the rejection. While it may be credible that the mouse can be used to study gene function, such a use is neither specific nor substantial as set forth in the previous office action. Furthermore, whether the federal courts have sustained other rejections under 35 USC 101 does not make the instant rejection improper and Applicant's argument is not effective in persuading the withdrawal of the rejection. Therefore, the utility of the instant invention is neither specific nor substantial.

Applicant also discloses the commercial use of the claimed mice and states that commercial use and acceptance is one important indication that the utility of an invention has been recognized by one of skill in the art (page 14 of Applicant's remarks). Applicant has submitted a declaration from Dr. Robert Driscoll stating that the mice have been sold to at least one large pharmaceutical company for the use of studying gene function and for human therapeutic drug development.

In response, the commercial use of the claimed mouse is not dispositive of the lack of a specific and substantial asserted utility in the original specification and does not provide evidence of a well-established use at the time the application was filed. Paragraph 4 of the declaration states that mice obtained from Deltagen are used for study of gene function and human therapeutic drug development. The declaration does not state that the claimed mouse is being used for any particular purpose. Despite this, as set forth above and in the previous office action mailed 01/13/2005, uses in study of gene function and human therapeutic drug

development for an unspecified disease, are not specific or substantial. Applicant is reminded that the requirements under §101 and §112, 1st para. must be met at the time the application is filed. There is no evidence in the declaration that the companies are using the mouse for any use identified in the specification. The discovery of an undisclosed use meeting these requirements after the application is filed does not satisfy the statutory requirements under either §101 or §112, 1st para. See *In re Kirk*, 153 USPQ 48, 52 (CCPA 1967); *In re Wright*, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993). The declaration filed does not provide any evidence that the requirements of a specific and substantial use were met at the time of filing.

Applicant has referred to the principles set forth in *In re Brana* (see pages 15-18 of Applicant's remarks). Applicant asserts that the specification supports a use of the knockout mouse that is specific and substantial in light of the teaching of *In re Brana.*

In response, the fact pattern in *Brana* does not correlate to the fact pattern of the instant application. In *Brana*, the court addressed two separate issues, utility and enablement. The court held that the specification did, in fact, disclose a specific and substantial use for the compound, treating leukemia, and that this use was overlooked by the PTO in making the rejection under 101. The court observed that the claimed compound was similar in structure to compounds in the prior art that were useful in treating leukemia. The claimed compound behaved in a manner similar to that of the prior art in art accepted assays for anti-leukemic activity. Therefore, the specification enabled the use. The instant specification and the art of record fail to support such a patentable utility for the instant invention and therefore, the principles set forth in *In re Brana* do not apply to the instant invention.

With respect to the basis of the rejection that the use of a mouse that is "less depressed" in screening for drugs is unclear as it relates to a real-world use, Applicant argues that the mouse has been delivered to at least one large pharmaceutical company and therefore, one skilled in the art know how to use it.

In response, at the time of filing, the teachings in the specification failed to define the identity of the gene that correlates to the EST set forth by SEQ ID NO:1. The basis for the sale of the mouse to a pharmaceutical company is not known. Applicant has failed to point to any teachings in the specification to support that the claimed mouse had a specific and substantial use at the time of filing.

Applicant argues that because the mouse displays an anti-depressive phenotype, an agent that down regulates the gene of the invention could be useful in treating depression.

In response, as set forth at pages 13-14 of the office action mailed 01/13/2005, the art at the time of filing taught that anti-depressants counter the natural response of a wild-type mouse of remaining immobile when held by the tail. However, the art of record fails to teach that decreased immobility in the tail suspension test correlates with a model of decreased propensity for depression (see page 13, last paragraph). There is no evidence supporting that a negative regulator of the gene that correlates to SEQ ID NO:1 would be a potential treatment for depression. The identity of the gene, its role in the cell, and its role in depression or any other behavior was not known at the time of filing. This, along with the teachings of Crawley (see pages 13-13 of the office action mailed 01/13/2005) indicates a clear need for further experimentation to determine that the claimed mouse can be used to identify agents for treating depression in humans. Furthermore, it is unclear how the skilled artisan would use the claimed

mouse as a test subject to identify downregulators of expression of a gene that is not present in the test subject.

In light of the above, the skilled artisan would not find the asserted utility of the transgenic mouse and cells and methods encompassed by the claims to be specific and substantial.

Enablement

Claims 8-10,18,21,23 and 36-39 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 8-10,18,21,23 and 36-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In addition to the reasons raised in the rejection made under 35 USC 101 for the specification failing to teach to use the claimed products and methods of making the claimed products, the claims further lack enablement for reasons set forth at pages 15-20 of the office action mailed 01/13/2005.

Applicant's arguments have been thoroughly considered and are partially persuasive as set forth below.

1) The aspect of the rejection based on the grounds that the claims encompass animal species other than mouse that are not enabled by the specification is withdrawn in light of Applicant's amendments to the claims (see pages 17-18 of the office action mailed 01/13/2005).

2) The aspect of the rejection pertaining to the breadth of phenotypes encompassed by the claims is maintained. Claims that fail to recite a phenotype encompass mice exhibiting any phenotype. The only phenotype taught by the instant specification is less time immobile in the tail suspension test. Applicant argues that the claims that do not recite a phenotype now recite that the allele is a null allele and that a null alleles in the gene correlating to SEQ ID NO:1 should exhibit the same phenotypes, overcoming the relevant enablement issues.

In response, addition of a limitation to the claims relating to the type of allele created does not effectively limit the scope of phenotypes encompassed by the claims. First, phenotypic limitations from the specification cannot be read into the claims. Second, the phenotype of the mice broadly encompassed by the claims is not predictable based on the guidance and teachings provided by the specification. The specification teaches knockout mice with a disruption in the gene that correlates to SEQ ID NO:1 that were generated using a 129/SvJ substrain of ES cells followed by breeding to C57BL/6 mice. Yoshikawa (2002) taught there are interstrain differences in baseline performance in the tail suspension test (paragraph bridging columns at page 357). Furthermore, Gerlai taught the differing effects of genetic background in correlating a gene mutation to a behavioral phenotype, such as performance in the tail suspension test [**TIGS,** 19:177-181,1996]. Mice of different genetic backgrounds were discussed in the instant specification. The claims encompass any genetic background and the performance of the claimed mice of different genetic backgrounds in the tail suspension test or any other assay may vary

from that taught in the specification. The specification does not teach the phenotype of the claimed mice of any genetic background other than those made using ES cells from an 129/SvJ substrain background and mating to C57BL/6 mice. The specification does not overcome the variability of results in the tail suspension test in wild-type mice as established by the art or the unpredictability of phenotype associated with making transgenic mice (see Leonard, 1995; Griffiths, 1998; office action mailed 01/13/2005; pages 16-17).

3) The aspect of the rejection pertaining to the claims encompassing secreted protein genes other than that correlating to SEQ ID NO:1 is withdrawn in light of Applicant's amendments to the claims.

4) The rejection on based on the phenotypes of claims 16-18 is maintained for claim 18 because the claim continues to encompass heterozygous mice. The heterozygous mice of the invention are not disclosed as displaying a phenotype that differs from wild-type as encompassed by claim 18.

5) The aspect of the rejection pertaining to chimeric mice is withdrawn in light of Applicant's amendments to the claims.

Written Description

The rejection of claims 5-10,16-21 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicants have limited the genera of genes encoding a secreted protein. However, the amendment has necessitated a new grounds of rejection as they introduce new matter into the specification as set forth below.

New Matter

Claims 8-10,18,21,23 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as

containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 8, as amended, is directed to a null endogenous secreted protein allele wherein the endogenous allele encodes an mRNA comprising the mouse homolog of SEQ ID NO:1. This is new matter. SEQ ID NO:1 is a DNA sequence, not an mRNA sequence. The specification and claims as originally filed do not describe an mRNA comprising the sequence set forth by SEQ ID NO:1. The specification does not describe or define any sequence corresponding to the homolog of the human gene correlating to SEQ ID NO:1.

Newly added claim 38 is drawn to the mouse of claim 8 wherein the null allele comprises a gene encoding a selectable marker. This claim encompasses both positive and negative selectable markers. The specification does not teach the claimed mouse comprising only a negative selectable marker. The specification teaches a construct comprising a positive selectable marker (neomycin resistance). Omission of the limitation of a positive selectable marker is new matter because the claim encompasses use of a negative selectable marker, alone or in addition to other markers, that is not taught by the instant specification.

MPEP 2163.06 notes, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is

clearly conveyed to those skilled in the art at the time the application was filed. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5-10,19 and 20 are withdrawn in light of Applicant's amendments to the claims. Neither Bucay nor Zhang taught a disruption in a gene that encodes SEQ ID NO:1.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER